

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0344]

DDM

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Center	A. Corbin

Draft Guidance for Industry and Food and Drug Administration Staff; Class

II Special Controls Guidance Document: Tinnitus Masker Devices;

Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Tinnitus Masker Devices." The draft guidance describes a means by which tinnitus masker devices may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the classification regulations for the tinnitus masker presently classified into class II (special controls: labeling) to designate a special control for these devices. The draft guidance is neither final, nor is it in effect at this time.

**DATES:** Submit written or electronic comments on this draft guidance by *[insert date 90 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Class II Special Controls Guidance Document: Tinnitus Masker Devices" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr.,

Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

Submit written comments concerning this draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Teresa Cygnarowicz, Center for Devices and Radiological Health (HFZ-460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-594-2980.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule to amend the classification regulations for tinnitus masker devices presently classified into class II (special controls: labeling) to designate a special control for the devices. The draft guidance document describes a means by which the device may comply with the requirement of special controls for class II devices. Following the effective date of a final rule based on the proposed rule, any firm submitting a 510(k) premarket notification for the device will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on tinnitus masker devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

To receive "Class II Special Controls Guidance Document: Tinnitus Masker Devices" by fax, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (1555) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>.

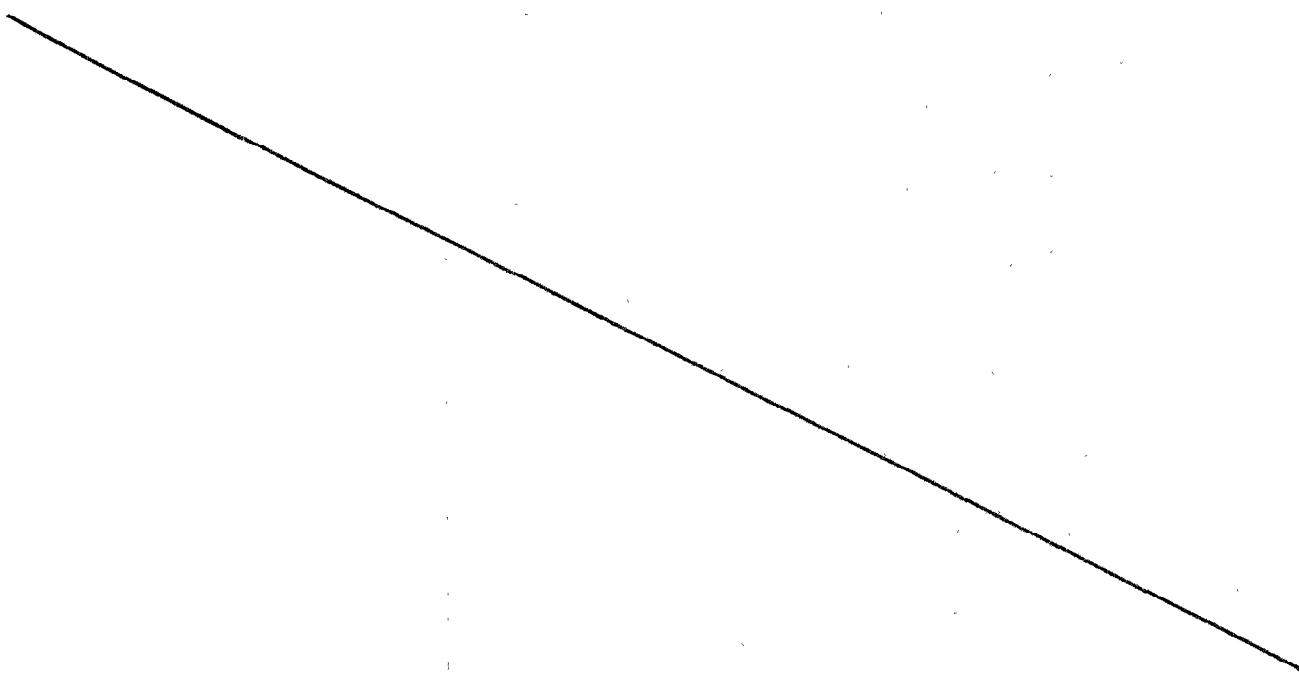
Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

#### **IV. Paperwork Reduction Act of 1995**

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E), under OMB control number 0910–0120. The labeling provisions addressed in the draft guidance have been approved by OMB under OMB control number 0910–0485.

#### **V. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of



this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 10/7/05  
October 7, 2005.

Linda S. Mahan

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